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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,857	07/25/2001	Charles D. Petrie	PC10843AMAG	6128

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/912,857	PETRIE ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *18-21, 26-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Request for Continued Examination filed October 23, 2003 is acknowledged and accepted. An Amendment filed October 23, 2003 is further acknowledged. Claims 1-12, 15-21 and 26-38 remain under consideration.

In response to the request for an Election of Species, Applicants have elected 2-amino-N-(2-(3a-(R)-benzyl-2-methyl-3-oxo-2, 3, 3a, 4, 6, 7-hexahydro-pyrazolo-[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl)-isobutyramide on February 16, 2004. The election of a particular condition of functional health status is withdrawn. Further, Applicants elected the omission of an additional agent of claims 26-38.

Accordingly, claims 18-21 and 26-38 are presently withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Re-affirmation of the elections is requested when Applicants respond to this Office Action. Claims 1-12 and 15-17 remain under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In the Amendment filed October 21, 2003, Applicants cite pages 5, 19 and 29-31 in the specification for support for the new

recitation "resulting from aging". However, the citations appear to be directed to the original recitation "age-related".

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 and 15-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims1-16 of copending Application No. 10/720977. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to methods for the improvement of functional health status comprising administering growth hormone secretagogues. The specification provides no support for the specific administration of

the compound, 2-amino-N-(2-(3a-(R)-benzyl-2-methyl-3-oxo-2, 3, 3a, 4, 6, 7-hexahydro-pyrazolo-[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl)-isobutyramide to improve functional health status.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to improving functional health status in a patient with a decline in physical performance.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the field of gerontology.

Each particular age-related decline in physical performance has its own specific characteristics and etiology. The broad recitation "improving functional health status" is inclusive of many conditions that presently have no established successful therapies.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to speculative conclusions drawn from growth hormone supplementation.

The breadth of the claims

The claims are very broad and inclusive of any growth hormone secretagogue for the improvement of any functional health parameter in an elderly population.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples directed to the administration of 2-amino-N-(2-(3a-(R)-benzyl-2-methyl-3-oxo-2, 3, 3a, 4, 6, 7-hexahydro-pyrazolo-[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl)-isobutyramide in a standardized test of physical performance in older adults. Such standardized tests are well known in the prior art.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which particular secretagogue would be preferred for improvement of a particular aspect of functional health status, as, for example, those set forth in claims 2-11. The skilled artisan would expect the administration of a particular growth hormone secretagogue for the improvement of a

particular aspect of functional health status to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding or any criteria for extrapolating beyond what is well established in the art. There is no support that the elected species referenced *supra* would be effective to improve any aspect of functional health status in the elderly. Absent reasonable *a priori* expectations of success for using a particular growth hormone secretagogue to treat any particular aspect of functional health status, one skilled in the gerontology art would have to test extensively many growth hormone secretagogues to discover which aspect of functional health status responds to that particular agent. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Applicants' arguments with respect to claims 1-21 and 26-38 that were rejected under 35 U.S.C. 103 as being unpatentable over WO 00/12047, in view of WO 97/24369, have been considered but are moot in view of the new ground of rejection.

Claims 1-12 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al., US 2002/0086868 (abstract).

Friedman teaches the oral administration of 2-amino-N-(2-(3a-(R)-benzyl-2-methyl-3-oxo-2, 3, 3a, 4, 6, 7-hexahydro-pyrazolo-[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl)-isobutyramide in methods for stimulating or increasing appetite. See page 9, paragraphs [0140], [0141], [0142], [0144] and [0147], where

growth hormone secretagogues are disclosed to be beneficial for various medical conditions that affect elderly people by improving the underlying endocrine and metabolic dysfunctions that lead to geriatric debilitation. Those aspects of functional health status, as recited in claims 2-11, are parameters one skilled in the art would have reasonably sought to improve. The claims differ with respect to Friedman's focus, i.e., his teaching that the administration of the growth hormone secretagogues of his invention stimulate or increase appetite. However, one skilled in the geriatric art would have been motivated to administer a growth hormone secretagogue, such as 2-amino-N-(2-(3a-(R)-benzyl-2-methyl-3-oxo-2, 3, 3a, 4, 6, 7-hexahydro-pyrazolo-[4,3-c]pyridin-5-yl)-1-(R)-benzyloxymethyl-2-oxo-ethyl)-isobutyramide, to improve functional health status in the elderly. Such would have been obvious in the absence of evidence to the contrary because elderly people often suffer from malnutrition due to poor appetite. According to Friedman's teaching, it would have been reasonable to expect a stimulation of appetite would have resulted in an improvement of functional status, as well as an improvement in the endocrine and metabolic dysfunctions that often characterize the decline in physical performance in the geriatric population.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis G. Spivack at telephone number 571-272-0585.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

May 16, 2004

PHYLLIS SPIVACK
PRIMARY EXAMINER